



Allen Amsler, *Chairman*
Ann B. Kirol, DDS, *Secretary*
R. Kenyon Wells

Board:
Charles M. Joye II, P.E.
L. Clarence Batts, Jr.
David W. Gillespie, MD

South Carolina Board of Health and Environmental Control

November 10, 2016

The South Carolina Board of Health and Environmental Control met on Thursday, November 10, 2016, at 10:00 a.m. in the Board Room of the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance:

Allen Amsler, Chairman, Member-at-Large
R. Kenyon Wells, 2nd District
L. Clarence Batts, 4th District
William Lee Hewitt, III, 7th District

By Phone:

Ann B. Kirol, DDS, Secretary, 5th District
Charles M. Joye, II, P.E., 3rd District
David W. Gillespie, MD, 6th District

1st District seat is currently vacant.

Also in attendance were Catherine E. Heigel, Director; W. Marshall Taylor, Jr., General Counsel; Lisa L. Longshore, Clerk; Department staff and a member of the public. (Attachment 0-2)

Chairman Amsler called the meeting to order and stated notice of this meeting had been provided to all persons, organizations and news media, which have requested notification, as required by Section 30-4-80(e) of the South Carolina Code of Laws.

Item 1: Minutes of October 13, 2016, meeting (Attachment 1-1)

Mr. Hewitt moved, seconded by Mr. Wells, to approve the minutes as presented for the October 13, 2016, Board meeting. The Board voted and Motion carried.

Item 2: Administrative and Consent Orders issued by Environmental Affairs (Attachment 2-1)

Ms. Robin Stephens, Compliance Assistance and Enforcement, Environmental Affairs, stated eighty-seven (87) Consent Orders had been issued with total penalties of \$200,097.

The Board accepted this item as information.

Item 3: Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation (Attachment 3-1)

Mr. Thomas Bowen, Senior Consultant, Health Regulation Policy and Communications stated four (4) Consent Orders and one (1) Emergency Suspension Order had been issued with total penalties of \$11,000.

The Board accepted this item as information.

Item 4: Public Hearing and Request for Final Approval – Proposed Amendment of Regulation 61-94, WIC Vendors, State Register Document No. 4671, Legislative Review is required (Attachment 4-1)

Mr. Berry Kelly, Director, Division of Women, Infants and Children (WIC) presented this item to the Board.

Mr. Kelly stated the published agenda for today's meeting had the incorrect State Register Document No. for this agenda item. *Clerk's Note: These minutes reflect the correct State Register Document No.*

The proposed amendment and update pertains to provisions included in the Child Nutrition and WIC Reauthorization Act of 2004. These provisions required the establishment of a vendor peer group system, distinct peer competitive price criteria, allowable reimbursement levels for each peer group and other vendor related provisions to ensure program integrity. In addition, a final rule, published by the United States Department of Agriculture, Food and Nutrition Services in the Federal Register on March 4, 2014, revised the WIC food packages. The proposed revisions align the WIC food packages with the Dietary Guidelines for Americans and infant feeding practice guidelines of the American Academy of Pediatrics. This rule also encompassed vendor related amendments. All of the vendor provisions and amendments were implemented to ensure adequate and appropriate monitoring of the Program's food delivery system to prevent fraud, waste and abuse from occurring and to safeguard program benefits.

A public hearing was conducted, and no one in attendance requested the opportunity to speak. (Attachment 4-2)

After discussion, ***Mr. Batts moved, seconded by Mr. Wells, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-94, WIC Vendors, and approve it for submission to the Legislature for review. The Board voted and Motion carried.***

A verbatim transcript of this proceeding is included as part of the record. (Attachment 4-3)

Item 5: Public Hearing and Request for Approval for Placement of synthetic opioid, 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide (also known as U-47700, "PINK"), into schedule I for Controlled Substances (Attachment 5-1)

Ms. Anne Marie Ravenna, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the S.C. Controlled Substances Act (CSA), found at Title 44,

Chapter 53, of the S.C. Code of Laws. Section 44-53-160 is titled "Manner in which changes in schedule of controlled substances shall be made." Pursuant to Section 44-53-160, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule I substances are listed in § 44-53-190. Section 44-53-160(B) provides a process by which DHEC can hold a public hearing and expeditiously designate a substance as a controlled substance if the federal government has not yet scheduled a substance.

§ 44-53-160(B) states:

"Except as otherwise provided in this section, during the time the General Assembly is not in session, the department may add, delete, or reschedule a substance as a controlled substance after providing notice and a hearing to all interested parties. The addition, deletion, or rescheduling of a substance pursuant to this subsection has the full force of law unless overturned by the General Assembly. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change."

The Administrator of the Drug Enforcement Administration issued its notice of intent to temporarily schedule the synthetic opioid, 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide (also known as U-47700, "PINK"), into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act on September 7, 2016. This action was based on a finding by the Administrator that the placement of this synthetic opioid into schedule I of the Federal Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. No final order has been issued as of the date the public hearing was noticed, but is anticipated at any time.

Based on the documented case reports of overdose fatalities, the abuse of U-47700 leads to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. This indicates that U-47700 poses an imminent hazard to the public safety.

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of U-47700 poses an imminent hazard to the public safety. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated April 18, 2016, notified the Assistant Secretary of the Department of Health and Human Services of the DEA's intention to temporarily place this substance in Schedule I. The Assistant Secretary responded, stating that HHS had no objection to the temporary placement of U-47700 into Schedule I of the Controlled Substances Act. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for U-47700 indicate that this substance meets all of these criteria.

This notice of intent issued by the Administrator initiates an expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule U-47700 in schedule I of the CSA, and finds that placement of this synthetic opioid into schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

A public hearing was conducted, with the following speaking: (Attachment 4-2)

Wendy Bell, SLED Forensic Services Laboratory
Eddie Hunter, 7th Circuit Assistant Solicitor
Melissa Hendrix, Chief Forensic Chemist, Spartanburg County

After discussion, ***Mr. Batts moved, seconded by Mr. Hewitt, to designate the additional substances as named in the DEA Notice of intent published in the Federal Register on September 7, 2016, and amend Section 44-53-190 of the S.C. Controlled Substances Act. The Board voted and Motion carried.*** Signed Designation Document – Attachment 5-3

A verbatim transcript of this proceeding is included as part of the record. (Attachment 5-4)

Chairman Amsler recognized Mr. Hewitt for his service to the Board and congratulated him on being elected to the S.C. House of Representatives to represent District 108.

Item 6: Agency Affairs

Director Heigel reported on the following:

- Agency wide activities and, specifically, on Dam Program activities during Hurricane Matthew;
- Executive Budget Office Hearing;
- Communications Office receiving Palmetto Award of Excellence for Government Communication Programs; and
- Announcement of Dr. Lillian Peake joining the agency as Deputy Director of Public Health.

Mr. Hewitt recognized the staff of Ocean and Coastal Resource Management Office for their work post Hurricane Matthew.

Mr. Batts moved, seconded by Dr. Gillespie, to go into Executive Session for the discussion of a legal matter pertaining to SRS. The Board voted and Motion carried.

Mr. Amsler announced the Board was back in public session and while in Executive Session no actions were taken.

Having no further business, Chairman Amsler adjourned the meeting.

All referenced attachments are made a permanent part of these minutes.

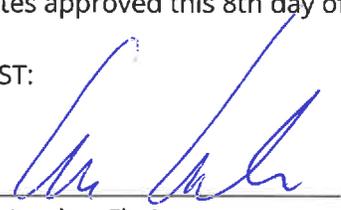
Respectfully submitted,



Ann B. Kirol, DDS, Secretary

Minutes approved this 8th day of December 2016.

ATTEST:



Allen Amsler, Chairman

Attachments

- 0-1 Agenda
- 0-2 Attendance Roster
- 1-1 October 13, 2016 minutes
- 2-1 Administrative and Consent Orders issued by Environmental Affairs
- 3-1 Administrative Orders, Consent Orders and Sanctions issued by Health Regulation
- 4-1 Public Hearing & Request for Final Approval Proposed Amendment of R.61-94, WIC Vendors
- 4-2 Public Hearing sign-in sheet
- 4-3 Verbatim Transcript
- 5-1 Public Hearing and Request for Approval for Placement of synthetic opioid, 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide (also known as U-47700, "PINK"), into schedule I for Controlled Substances
- 5-2 Public Hearing Sign-in Sheet
- 5-3 Board Designation Document
- 5-4 Verbatim Transcript